DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
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Minneapolis, MN 55401
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July 11, 2006

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 06 - 27

John Hinson
President and CEO
Cardiac Science Corporation
3303 Monte Villa Parkway
Bothel, WA 98201

Dear Mr. Hinson:

During an inspection of your establishment located in Deerfield, Wisconsin, between April 11 and 26, 2006, investigators from the U.S. Food and Drug Administration (FDA) determined that your establishment manufactures Automated External Defibrillators (AEDs). AEDs are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), because they are intended for use in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, [21 U.S.C. § 351(h)], in that the methods used in, or the facilities or controls used for, their manufacturing, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation for medical devices found at Title 21, Code of Federal Regulations (CFR), Part 820. We received a response from Cheryl L. Shea, Vice-President of Regulatory Affairs/Quality Assurance, dated May 10, 2006, concerning our investigators' observations noted on the Form FDA 483, List of Inspectional Observations, that was issued to Ms. Shea at the close of the inspection. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to adequately maintain procedures to control product that does not conform to specified requirements and a failure to adequately maintain procedures for rework to ensure that the product meets its current approved specifications, as required by 21 CFR §§ 820.90(a) and (b)(2). Specifically, Printed Circuit Board Assemblies (PCBAs) were supposed to be quarantined pending before use. However,

these PCBAs were used in finished AEDs, which were then distributed. The distribution of these AEDs resulted in a recall. (FDA-483 Item 2).

Your response to this observation appears to be adequate.

2. Failure to adequately validate with a high degree of assurance and approve according to established procedures a process that cannot be fully verified by subsequent inspection and test, as required by 21 CFR § 820.75(a). For example, Printed Circuit Board Assembly (PCBA) 120-2060-002 was not validated after changes were made and the Rev C board was released for production on 4/23/04. (FDA-483 Item 1).

Your response to this observation appears to be adequate. However, FDA is concerned that you did not attempt to adequately validate the PCBA near the time of your merger with Cardiac Science, Inc. (CSI). Indeed, the lack of validation was discovered during the inspection, which was approximately seven months after the merger.

3. Failure to maintain procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100(a). For example:

   A. No CAPA investigation was opened for the [redacted] complaints received in a recent five month period relating to the [redacted] on PCBA 120-2060-002. (FDA-483 Item 3).

   B. No CAPA investigation was opened to investigate the [redacted] rate for the PCBA 120-2060-002 found during visual inspection of product at the receiving stage. (FDA-483 Item 3).

   C. No CAPA was opened to investigate/evaluate [redacted] as an acceptable PCBA supplier. (FDA-483 Item 3).

   D. CAPA #379 was not adequately investigated. CAPA #379 erroneously concluded that the AED "labeling describes not to remove the battery when the AED is running." However, the Instructions For Use Manual states that "[w]hen the AED battery cannot deliver any more shocks, the AED display will show 'BATTERY LOW' . . . . To continue the rescue, leave the lid open, remove the battery, and replace with a fresh battery." (FDA-483 Item 5).

We have reviewed your responses to Items 3 and 5 and have concluded that they are inadequate because they fail to address the fact that a malfunction of this nature can result in failure of the device to function.

4. Failure to maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements as required in 21 CFR § 820.50. For example, the firm has not addressed the issue of quality requirements on incoming product, when the vendor is shipping a

significant quantity of boards that are not passing inspection. (FDA-483 Item 4).

We have reviewed your response and have concluded that it is inadequate because you have failed to describe or explain the corrective measures you intend to take when the vendor is shipping a significant quantity of boards that are not passing inspection.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and FDA regulations. The specific violations noted in this letter and in the Form FDA-483 may be symptomatic of serious underlying problems in your establishment's Quality System. You are responsible for investigating and determining the causes of the violations. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the devices have been corrected.

You should take prompt action to correct your deviations from the Act and FDA regulations. Failure to promptly correct your deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Jane Nelson, Compliance Officer, Food and Drug Administration, 212 Third Avenue South, Minneapolis, MN 55401.

Sincerely,

W. Charles Becoat

W. Charles Becoat
Director
Minneapolis District

JEN/ccl